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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,075	01/14/2000	DANIEL COHEN	GENSET.020AP	5833

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1655

DATE MAILED: 01/22/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,075

Applicant(s)

COHEN ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86,88,89 and 92-121 is/are pending in the application.
- 4a) Of the above claim(s) 106-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 86,88,89 and 92-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Upon consideration of applicant's argument, prosecution on the merits is hereby reopened. New grounds of rejection follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 86, 88, 89, and 92-105 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goelet et al.

7. Goelet et al., disclose a method whereby single nucleotide polymorphisms (SNPs) can be detected in any plant or animal, including humans, and that these sites are useful in determining "identity, ancestry, predisposition to genetic disease, the presence or absence of a desired trait, etc." (abstract). Goelet et al., page 14, first paragraph, teach that SNPs occur "approximately once every 300 bases in the mammalian genome, and exhibit uniformity of distribution, a SNP can, statistically, be found within 150 bases of any particular genetic lesion or mutation. Indeed, the particular mutation may itself be an SNP. Thus, where such locus has been sequenced, the variation in that locus' nucleotide is determinative of the trait in question." Such a disclosure meets the limitation that the polymorphisms have a heterozygosity rate of "at least about 0.18 and having a mean inter-marker spacing of less than 50 kb" (claim 86).

8. As presently worded, claim 86 requires that the genomic library comprise either a) the entire human genome; or b) fragments that comprise at least 100 kb. For purposes of examination, the above phrases have been further interpreted as allowing for any size of

individual fragments so long as the overall size of the genomic fragment represented in the aggregate of said fragments is "at least 100 kb" and can be as large as the entire human genome.

9. Goelet et al., page 16, disclose that they use libraries of genomic fragments wherein the individual fragments have a length of from 0.5 to 3.0 kb and that "such genomic libraries (typically of approximately 50,000 clones), several hundred (200-500) individual clones are [analyzed]." Such a showing meets the limitation of the present claims as it relates to the overall size of genomic DNA present in the library.

10. With but a single library of Goelet et al., giving rise to 5,000 SNPs ((500 individual clones x 3,000 b) / 300 b/SNP), and with a single library providing an analysis of but a small portion of the human genome, and with Goelet et al., fairly teaching that the entire genome can be scanned for SNPs, the aspect of one of skill in the art identifying "at least 20,000 single nucleotide polymorphisms" (claim 94) is fairly suggested.

11. The aspect of performing genetic analysis so as to determine if SNPs are in linkage equilibrium, or disequilibrium, is disclosed at pages 36-45.

12. Goelet et al., do not explicitly teach the heterozygosity rate of claims 92 and 93, however, the heterozygosity rate is that of the SNPs to be identified and are an inherent characteristic of the human DNA being evaluated. Since Goelet et al., fairly teach identifying all SNPs of any animal, including that of humans, the SNPs being identified would have as an inherent property, the heterozygosity rates set forth of claims 86, 92 and 93, and by extension, any claim that depends therefrom.

13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 86, 88-89, and 92-105 are considered to be anticipated by the disclosure of Goelet et al., and in

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the event that such disclosure does not anticipate the claimed invention, such would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the detailed guidance provided.

Conclusion

14. Rejections which appeared in the prior Office action and which were not repeated hereinabove have been withdrawn.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
January 21, 2002